# STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

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## Addendum: Interim Guidance for Abbott BinaxNOW™ COVID-19 Antigen Card Recipients in Connecticut – October 14, 2020

This document provides interim guidance for the use of the Abbott BinaxNOW™ SARS-CoV-2 antigen test from the State of Connecticut, which has Emergency Use Authorization (EUA) from the U.S. Food & Drug Administration (FDA). This document is an addendum to Interim Guidance for SARS-CoV-2 Antigen Testing and Reporting in Connecticut released by the Connecticut Department of Public Health (DPH) on September 29, 2020.

"Rapid" antigen testing for SARS-CoV-2 can be helpful and lead to more timely contact tracing and testing when timely turnaround times for molecular reverse transcription polymerase chain reaction (RT-PCR) results are not achievable. Antigen tests can provide point-of-care (POC) diagnosis for individuals presenting with possible COVID-19 infection. Detection of viral antigen is generally less sensitive than nucleic acid detection using RT-PCR however, which could lead to erroneous results.

### Summary of Guidance

- **Recipients should review and understand DPH's Interim Guidance for SARS-CoV-2 Antigen Testing and Reporting in Connecticut.**
  - **Ordering providers should be familiar with the performance characteristics of the BinaxNOW™ and follow manufacturer's instructions for specimen collection and handling.**
  - **DPH recommends adhering to the manufacturer's "intended use" (patients with symptoms suggestive of COVID-19 within the first 7 days of symptom onset) as described in the Instructions for Use.**
  - **Until more data are available, all negative BinaxNOW™ results in patients with high suspicion (pretest probability) for COVID-19 should be confirmed by a RT-PCR test for SARS-CoV-2.**
  - **DPH recommends confirming positive antigen results with RT-PCR when suspicion for COVID-19 is low due to the potential for false positives.**
  - **Positive antigen results do not necessarily need confirmation by RT-PCR when suspicion for COVID-19 is high.**
- **Personnel involved in the collection and handling of specimens must complete Abbott's training modules.**
- **Appropriate PPE must be used for specimen collection and handling, and PPE must be provided by the testing institution.**
- **An active CLIA Certificate of Waiver is required before conducting POC antigen testing, and DPH's attestation form must be submitted to DPH.FLISLab@ct.gov.**
- **Any institution receiving BinaxNOW™ tests from the State of Connecticut must report ALL test results (positive and negative) to DPH in an *electronic* format as specified by DPH. Additional case reporting is required for all positive SARS-CoV-2 findings.**

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- **Patients must be counseled on the interpretation and implications of their result, whether positive or negative.**
- **Patients must be provided the Patient Fact Sheet for the BinaxNOW™, as this is a test that has received EUA from the FDA.**
- **Patients must be provided results in written form (hard copy or secure electronic format). For options, explore Abbott's Navica™ smartphone application or CDC's "Ready, Set, Test" booklet.**

## Considerations for SARS-CoV-2 Testing with the Abbott BinaxNOW™

Test sensitivity generally wanes as time from symptom onset increases. Sensitivity data for antigen tests with FDA EUAs are generated from comparisons with RT-PCR (percent positive agreement with gold standard). These data are from testing specimens collected from patients who presented with symptoms suggestive of COVID-19.[1]

Ordering providers should carefully review the "Limitations" section of the Instructions for Use. They can also find sensitivity data in the "Clinical Performance" section.

- Clinical performance and the potential need to pursue confirmatory testing should be considered when discussing antigen testing with patients and making decisions regarding the use of antigen testing.
- For the BinaxNOW™, there is no published performance data for patients under the age of 22 years (as of October 10, 2020).
- Data for testing of asymptomatic individuals is limited.

Sensitivity data may change with further validation studies. FDA has a SARS-CoV-2 Reference Panel for comparing sensitivities.

Personnel involved in collection should be trained to follow the instructions for use. Specimen quality can vary with specimen collection technique, particularly with self-collection. FDA does not specifically authorize self-collection for the BinaxNOW™. If self-collection is done, due to potential for inadequate sampling, FDA recommends providing clear instructions to patients who self-collect their specimens under observation.[2]

## Testing Individuals *Without* COVID-19 Symptoms

**A highly sensitive test (i.e., RT-PCR) should be considered when screening asymptomatic individuals.** If such testing is not feasible, or if turnaround times are prolonged, using antigen tests for screening asymptomatic individuals can be considered even if they are not specifically authorized for this indication (commonly referred to as "off-label" use).[3]

If a clinician or facility would like to screen asymptomatic individuals for SARS-CoV-2 using antigen tests, DPH recommends consulting an expert in laboratory medicine or infectious diseases. The DPH Infectious Diseases Section can also offer guidance, however DPH does not currently have recommendations for asymptomatic screening using antigen tests for SARS-CoV-2 beyond the nursing home setting, for which the Centers for Disease Control and Prevention (CDC) has guidance for serial screening.[4]

DPH recommends confirming positive antigen results with RT-PCR when pretest probability is low (e.g., asymptomatic person, no ongoing outbreak in a facility, low community incidence) due to the potential for false positives. In this situation, the individual with the positive antigen result should be isolated away from others while awaiting confirmatory testing results. In congregate settings, this person should not be cohorted with individuals who could be infectious with COVID-19 until RT-PCR confirmatory results are available.

## Counseling Patients About Antigen Testing

Given tests with EUA have not undergone the same type of review as an FDA-approved or cleared diagnostic test, **all facilities are mandated by the FDA EUA to provide antigen test fact sheets to healthcare providers performing/ ordering the test and patients undergoing COVID-19 testing.** These fact sheets can be found on the FDA website. Providers should also discuss with patients the reasons for confirmatory testing with RT-PCR, as applicable, given the performance characteristics of the antigen test.

## Requirements Before Antigen Testing Starts

**Healthcare Providers using point-of-care devices under FDA-EUA are required to have an active Clinical Laboratory Improvement Amendment (CLIA) Certificate of Waiver from CMS.**

Facilities with active CLIA Certificate of Waiver:

1. Complete the **DPH's FDA-EUA attestation form** and return to DPH.FLISLab@ct.gov prior to testing patient samples.
2. Submit a sample of a patient test report OR dummy patient chart OR a narrative as to how the results are being recorded along with the above attestation form.
3. Please also indicate how the test fact sheets for healthcare providers and patients are distributed (via hard copy or electronic link). Fact sheets are available from the manufacturer and on the FDA website.

Facilities with no active CLIA Certificate of Waiver:

1. Complete a CMS 116 Application form and return to DPH.FLISLab@ct.gov. DPH will notify the facility of their CLIA number immediately after entering into the CMS database.
2. Follow steps 1 & 2 above (for facilities with active CLIA Certificate of Waiver).

## Federal and State Reporting Requirements

Public Law 116-136, § 18115(a), the Coronavirus Aid, Relief, and Economic Security (CARES) Act, requires "every laboratory that performs or analyzes a test that is intended to detect SARS- CoV-2 or to diagnose a possible case of COVID-19" to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS).[5] Under HHS guidance, locations offering point-of-care testing are considered "laboratories", and reporting to HHS is accomplished by transmitting data to state or local public health departments.

**DPH has published guidance for reporting ALL COVID-19 results, both positive and negative, to fulfill both federal and state reporting mandates.** Test results should be reported to DPH electronically using either HL7 or flat file methods. These options are described in the reporting guidance. Outpatient settings should refer to the section **"COVID-19 Result Reporting by Point of Care Providers or Other Testing Locations"** in the reporting guidance.[6]

**In addition to reporting point of care test results, healthcare providers must also submit a COVID-19 Case Report Form for each positive test result they receive for a patient.**

- **If a positive antigen result is followed by a negative PCR result, a case report form still needs to be submitted for the positive antigen result.** DPH will receive the negative PCR result through laboratory reporting. These data help public health officials understand the use and impact of antigen testing.
- Providers performing point of care testing can include positive case report information in electronic files as described in the reporting guidance.
- Providers can also submit individual reports for patients with a positive result to a secure online portal at https://dphsubmissions.ct.gov/Covid/InitiateCovidReport.

## Counseling Symptomatic Patients to Self-Isolate at Time of COVID-19 Testing

Symptomatic patients should be counseled to self-isolate.

- Discuss the need for isolation immediately, even before results are available (if RT-PCR result pending). This means wearing a mask and limiting interactions with others as appropriate.
- Discuss importance of informing immediate household members that they too should be tested for COVID-19. Review locations and people for possible exposures within the past 2 weeks.
- Review of COVID-19 signs and symptoms.
- Encourage them to provide information to a contact tracer if they test positive and are called.
- Discuss services available to them to aid in isolating at home.

Providers who are eligible to bill CMS for counseling services can use existing evaluation and management (E/M) payment codes for CMS reimbursement for counseling about isolation at the time of testing. Please refer to **CMS' counseling checklist:** https://www.cms.gov/files/document/counseling-checklist.pdf

## Counseling Patients After a Significant Exposure to COVID-19

Anyone, whether symptomatic or not, who has had a significant exposure to someone with COVID-19 should self-quarantine at home for 14 days (maximum incubation period) after their last exposure. A significant community exposure is generally considered as close contact < 6 feet for ≥ 15 minutes, *regardless of mask use*.[7] Risk assessment for healthcare personnel considers PPE use.[8]

Quarantined individuals should stay home, at least 6 feet away from others, and avoid contact with people at higher risk for severe illness as they self-monitor for symptoms.

- If symptoms develop during the 14-day quarantine, the individual should follow home isolation guidance for COVID-19 infection and seek medical care and testing.
- A person who tests negative during their 14-day quarantine period should continue to self-quarantine until the end of their 14-day quarantine period.
- If an individual does not develop symptoms during the 14-day quarantine period, then they may be released from self-quarantine at the end of the 14-day period without the need for clearance testing.

## References


[1]CDC. Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html#clinical-presentation

[2]FDA. Recommendations on Providing Clear Instructions to Patients Who Self-Collect an Anterior Nares (Nasal) Sample in a Health Care Setting for SARS-CoV-2 Testing - Letter to Health Care Providers: https://www.fda.gov/medical-devices/letters-health-care-providers/recommendations-providing-clear-instructions-patients-who-self-collect-anterior-nares-nasal-sample

[3]FDA. FAQs on Testing for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

[4]CDC. Considerations for Use of SARS-CoV-2 Antigen Testing in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-antigen-testing.html

[5]HHS. COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115: https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

[6]CT DPH. Reporting SARS-CoV-2 (COVID-19) Test Results and Cases: Guidance for Laboratories, Point of Care Providers, and Others: https://portal.ct.gov/-/media/DPH/HAI/COVID19-Test-Reporting_092020V11.pdf

[7]CDC. Public Health Guidance for Community-Related Exposure: https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html

[8]CDC. Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

**Additional Guidance**

CDC: Interim Guidance for Rapid Antigen Testing for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

FDA: Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen

Association of Public Health Laboratories (APHL): Considerations for Implementation of SARS-CoV-2 Rapid Antigen Testing: https://www.aphl.org/programs/preparedness/Crisis-Management/Documents/APHL-SARSCov2-Antigen-Testing-Considerations.pdf

CDC: Ready, Set, Test Booklet for Waived Tests: https://www.cdc.gov/clia/docs/waived-tests/ready-set-test-booklet.pdf